



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1552d

Telephone (973) 526-6010

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

July 25, 2001

**WARNING LETTER**

**Certified Mail**  
**Return Receipt Requested**

Mr. Frank Polizzi  
Vice President of Operations  
Parmalat/Farmland Dairies  
520 Main Avenue  
Wallington, New Jersey 07057

**File No.: 01-NWJ-33**

Dear Mr. Polizzi:

An inspection of your facility, located at 520 Main Avenue, Wallington, NJ, was conducted from November 16-21, 2000. During this inspection, our investigators collected a sample of your Westbrae Natural Rice Beverage product, lot 191101FD-397930. Our review of your label and our analysis revealed that the product is considered misbranded according to Section 403(a)(1) and 403(r)(1)(A) of the Federal Food, Drug & Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Sections 101.9 and 101.54(e).

Our analysis found that the product contained significantly less than the labeled amounts of calcium and phosphorus. The Reference Daily Intake (RDI) of both calcium and phosphorus are 1,000 milligrams. Your label declares 25%DV (25% of the RDI) for calcium and 10%DV (10% of the RDI) for phosphorus. Our laboratory has reported original and check, and additional results of 16.1%, 9.64%, and 21% of the declared amount of calcium and 31.6%, 23.5%, and 39.2% of the declared amount of phosphorus. These values correspond to %DV results of 4.02%, 2.41%, and 5.25% for calcium and 3.16%, 2.35%, and 3.92% for phosphorus.

In addition, the product label bears the nutrient content claim "Enriched...with...Calcium" but the product does not qualify for this claim, in part, because it contains less than 10% of the DV of calcium per eight fluid ounce serving.

The above violations are not meant to be an all-inclusive list of deficiencies on your label or at your facility. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA and manufactured in accordance with all applicable regulations.

Please notify this office within 15 working days of receipt of this letter outlining the specific steps you have taken to correct the violations noted above and to prevent their recurrence.

Parmalat/Farmland Dairies  
Wallington, New Jersey 07057

Warning Letter 01-NWJ-33

-- Page Two --

If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the correction. Please submit your response to: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

*Edward H. Ellsworth, for*  
Douglas I. Ellsworth  
District Director  
New Jersey District